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| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/698,808

Applicant(s)

ADEOKUN ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-46 is/are pending in the application.
- 4a) Of the above claim(s) 34-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-33 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claim 31, particularly with regard to the SNP at position 1561 of SEQ ID NO: 1 is acknowledged. Claims 13-30, 32, 33 and 46 will be examined with the elected group as these are treated as linking claims in the restriction. Claims 33 and 46 are withdrawn from prosecution for requiring the assay of a non-elected combination of SNP, namely all of the SNP listed in the claim. Thus, claims 13-33 and 46 are examined in this office action.
2. Applicants traverse the election to the extent that it requires the election of a single polymorphism. However, this is not an entirely accurate characterization of the restriction, as the requirement was for the election of a single combination of polymorphisms as set forth on pages 3-4 of the requirement. Applicant elected a combination that includes only a single polymorphism, namely that at position 1561 of SEQ ID NO: 1. If this "combination" is determined to be free of the prior art, all combinations which include the elected combination will be rejoined to any claim which is determined to be allowable. Nonetheless, applicants traverse the restriction requirement stating that "a single sequence search can be used to search for prior art." This is not persuasive. The claims do not require the sequencing of a single sequence, but instead require looking only at particular positions of a sequence without requiring further context. Furthermore, the search for disclosure of single nucleotide polymorphisms and variants is not satisfied by a "single sequence search" as applicant purports. Fragments of surrounding each polymorphic site are required to be searched with each variant separately searched in order to ensure retrieval of relevant, indexed sequence data. Further, however,

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sequence polymorphism is often not indexed in traditional sequence search, so for each polymorphism separate analysis of the prior art for each position, including consideration of tables and text disclosure which describes variants must be undertaken. This is an enormous burden on the examiner and on USPTO resources. Further, this is not persuasive because even though all of the single nucleotide polymorphisms are within the same gene, they each would assert their own effect on the activity of the nucleic acid sequence which they are contained within, they each have distinct potential prognostic and/or diagnostic effects, and many of them lead to changes in the coding sequence which will lead to the production of proteins whose functionality is unknown. Any appropriate rejoinder will be considered when claims are found allowable. Thus, since the claims requires only the sequencing of a single position, and all twenty-eight of the recited positions are independent and distinct from one another and the search and examination of all twenty-eight separately would pose a significant burden to the examiner, the requirement that applicant select a single combination of polymorphisms for examination is proper and maintained. The requirement is therefore made FINAL.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Detection of Polymorphisms in the Human OATPC Gene.

4. The specification is not in compliance with the sequence rules. There is a sequence recited on page 18 of the specification that is not identified with a proper sequence identifier.

Claim Objections

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5. Claim 32 is objected to because it recites the determination of the presence or absence of "at least one" of the recited nucleotides in the alternative, and thus encompasses non-elected combinations of polymorphisms. Claim 32 was considered only insofar as it requires determining the identity of combinations that include the nucleotide at position 1561 of SEQ ID NO: 1.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-33 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-33 and 46 are indefinite because the preamble of claim 13 recites a method for determining the presence or absence of a single nucleotide polymorphism, but the method steps of the claims do not clearly set forth that this recited goal is accomplished. For example, claim 13 recites a final process step requiring a step of testing the sample to determine the identity of the nucleotide. The claims do not clarify how the testing step which results in determining the identity of the nucleotide results in determining the presence or absence of a single nucleotide polymorphism. A single nucleotide polymorphism is a variant that occurs among different individual's nucleic acid sequences at a particular position in the genome, so it is not clear how determining the nucleotide present at a particular position accomplishes the goal of determining the presence or absence of a SNP in a gene. That is, it is unclear how one practicing the

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invention knows from the testing step whether one has in fact determined the presence or absence of a single nucleotide polymorphism. Claims 22-30 and 32 are similarly indefinite.

All of the claims are further indefinite because it is unclear what is meant by a position "corresponding" to position 1513 of SEQ ID NO: 2, and all of the examined claims either recite this language or depend from a claim that recites this language. Is applicant referring only to position 1513 of SEQ ID NO: 2 or are other positions within SEQ ID NO: 2 within the scope of this recitation? To have a position "corresponding" to position 1513 of SEQ ID NO: 2, does a nucleic acid simply have to have 1513 nucleotides or is some other structural limitation implied by the use of this language?

Claim 33 is indefinite because it refers to "all 28 of the nucleotides" but the claim only sets forth 24 nucleotides.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 19, 20, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

With regard to claims 19, 20, 28, and 29 the new limitation of "the nucleotide is not a G" in claims 19 and 28 and the recitation "the nucleotide is in a codon that does not encode a glycine" in claims 20 and 29 appear to represent new matter. In applicant's remarks filed with the amendment, applicant asserts that support for these claims can be found in the table on page 14. This provides basis for a limitation wherein the nucleotide at position 1651 of SEQ ID NO: 1 is an G or a C, and basis for a codon that encodes glycine or arginine, however none of them provide specific basis for the limitation that the nucleotide is "not a G" or that the codon "does not encode a glycine." The language of these claims encompasses additional alleles at this position. For claims 19 and 28 the negative limitation encompasses at least two different nucleotide alleles that the specification does not provide written description as being present at position 1651 of SEQ ID NO: 1. For claims 20 and 29 the claims additionally encompass changes in the other nucleotides that are within the codon that position 1651 is a part of, providing that the changed "codon does not encode an glutamate," and also a variety of changes at any or all nucleotide positions within the codon that would result in any possible codon being present. Specifically, the exclusionary proviso in which the nucleotide is "not an A" or "does nor encode an glutamate" is not found in the specification. As noted by MPEP 2173.05(i),

"Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli* , 231 USPQ 393 (Bd. App. 1983) *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement."

Since no explicit basis has been identified for the newly added negative limitation, claims 19 and 24 are rejected as incorporating new matter.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 13-33 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Nature of the Invention and Breadth of the Claims

The claims are all drawn to methods which include a step of detecting a single nucleotide polymorphism within the human OATP-C gene. The particular polymorphism is an G→C transition at position 1516 of SEQ ID NO: 1. Rejected claims 13-21 require that the nucleic acid

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sample assayed be obtained from a “human identified as in need of treatment with a therapeutic agent that is transported by OATP-C.” Rejected claims 22-24 require that the nucleic acid sample be obtained from a person having or at risk of having or developing a “OATP-C mediated disease.” Thus, the “use” of this invention requires the knowledge of the relationship between the polymorphism at position 1113 of SEQ ID NO: 4 and some phenotype, for example, a disease or response to a drug. Furthermore, the practice of the claimed invention requires the knowledge of “a therapeutic agent that is transported by OATP-C,” or the knowledge of diseases which are in fact “OATP-C mediated.”

Rejected claims 14-21 require that the nucleic acid sample assayed be obtained from an individual identified as “in need of treatment with a therapeutic agent that is transported by OATP-C.” Thus, the nature of the invention requires the knowledge of drugs that are transported by OATP-C, and the scope of the claim includes persons in need of treatment with any possible therapeutic agent that is transported by OATP-C. Further, the implication of the claim is that the identity of the nucleotide will be useful for determining treatment for the human, and indeed, the specification states that “preferably determination of the status of the human is clinically useful (p. 10, line 27),” describing such utilities as determining what drug to administer or effective amounts of drugs. Most of the claims are sufficiently broad so as to encompass any possible drug that is “transported by OATP-C,” and any reason for treatment with such a drug.

Rejected claims 22-24 require that the sample is from a human “having or at risk for developing an OATP-C-mediated disorder.” Thus, the nature of the claimed invention requires knowledge of the identity of disorder which is in fact mediated by OATP-C, but the claims are sufficiently broad to include any possible disorder that is so mediated. Dependent claims 23 and

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24 narrow the scope of the disease to hyperlipoproteinemia or cardiovascular disease. Even this recitation is sufficiently broad so as to encompass many different diseases.

State of the Prior Art

The prior art teaches some polymorphisms in the human OATPC gene (see for example Laubert *et al.* (WO 00/08157) and Tamai *et al.* (Biochemical and Biophysical Research Communications 273, 251-260, 2000)). However, neither of these provide any characterization of the how these polymorphisms effect the activity of the OATPC encoded polypeptide. The prior art does not provide specific guidance with regard to the polymorphism identified herein as being at position 1561 in a sequence of the OATPC gene as defined by the position in SEQ ID NO: 1. The prior art teaches that OATP-C transports statins (Hsiang *et al.*). The prior art does not teach that OATP-C transports any other known "therapeutic agents." Further, the prior art does not establish any disease as being mediated by OATP-C.

Direction Provided in the Specification and Working Examples

The specification teaches that the polypeptide encoded by the OATPC gene is involved in multifunctional transport of organic anions, and in particular has been demonstrated to be involved in the transport of some xenobiotics and statins, as well as thyroid hormones and conjugated steroids. Further, the specification provides 24 polymorphisms in the OATPC gene, 4 of which result in amino acid changes. In particular, the specification teaches a polymorphic site at position 1561 in a sequence of the OATPC gene as defined by the position in SEQ ID NO: 1, located in exon 10 of the OATPC gene. The polymorphism is a single nucleotide polymorphism which results a substitution of arginine for glycine in the expressed protein (p. 14 of the specification). The specification is silent with respect to the effect of this polymorphism

on the biological activity of the OATPC gene, beyond the fact that it results in an amino acid substitution. The specification does not discuss or demonstrate how this substitution effects the activity of the encoded polypeptide nor does the specification discuss or demonstrate the effect of any of the other recited polymorphisms on the biological activity of the gene. The specification does not disclose any relationship between the presence of this polymorphism a change in the activity or expression of the OATPC or between the presence of a particular allele of this polymorphism and any particular disease state or physiological condition.

The amount of direction or guidance presented in the specification with regard to how to use the instant invention is minimal. With regard to claims directed towards simple detecting the presence of the gene polymorphism, applicant speculates that “one approach is to use knowledge of polymorphisms to help identify patients most suited to therapy with particular agents (this is termed “pharmacogenetics”) (p. 2),” but the specification does not elucidate the particular effects of any of the instantly disclosed polymorphisms on a response to drug therapy. Since the effects of any given polymorphism on gene activity are highly unpredictable, it is impossible to predict from the teachings of the instant specification what identifications can be made using the instantly claimed methods. That is, the specification does not provide any guidance as to how the polymorphism at position 1561 in a sequence of the OATPC gene as defined by the position in SEQ ID NO: 1 would be associated with any pharmaceutical agent. The specification does not discuss whether this particular polymorphism will increase the likelihood of a positive or negative response to any drug. Only one type of therapeutic agent, namely statins, were established as being transported by this molecule at the time the invention was made. There is no showing of a predictable relationship between this the allele present at position 1561 of SEQ

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ID NO: 1 and response to statins. Furthermore, the specification does not provide any guidance as to what disease is in fact mediated by OATPC. Any reference to such diseases in the specification is speculative. The specification does not demonstrate any disease associated with the presence or absence of the polymorphism at position 1561 in a sequence of the OATPC gene as defined by the position in SEQ ID NO: 1, other than the suggestion that these methods could be carried out for "OATPC mediated diseases." The specification provides no guidance or working examples that teach or demonstrate the ability to use the disclosed polymorphic site as a marker for any disease in particular, or for disease in general, or how to use to assess the pharmacogenetics of a drug transportable by OATPC.

Level of Unpredictability and Skill in the Prior Art

There is also a large body of knowledge in the prior art related to polymorphisms in general, and their association with diseases or disease states. The art is highly unpredictable with regard to the functionality of polymorphic sites in genomic DNA. After a screening assay identifies polymorphisms, it is unpredictable whether any such polymorphisms would be associated with any phenotypic trait, such as a disease state, a physiological state, or the processing of a drug (i.e. pharmacogenetics). For example, Hacker et al. were unable to confirm an association between a gene polymorphism and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (Gut, 1997, Vol. 40, pages 623-627). Even in cases where an association between a particular gene and a disease state is known to exist, such as with the LPL gene and heart disease risk or the β -globin gene and sickle cell anemia, researchers have found that when using SNP (single nucleotide polymorphism analysis) it was difficult to associate SNPs with disease states

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or to even identify key genes as being associated with disease (Pennisi, Science, 281 (5384):1787-1789). Finally, in some cases where multiple polymorphisms are identified in a gene, some of these are demonstrated to be disease associated and some are not. Blumenfeld et al. (WO 99/52942) disclose a number of polymorphisms in the FLAP gene. While Blumenfeld et al. were able to demonstrate that some of these polymorphisms are associated with patients having asthma but some of these are not (see Figure 3). For example, the marker 10-35/390 was demonstrated to be associated with asthma, with a p value of 0.00229, while the marker 10-33/327 was determined to not have a statistical association with asthma ($p=0.294$). Thus, even for SNPs within the same gene, it is highly unpredictable as to whether a particular marker will be disease associated.

Indeed, the post filing date art, for example Nozawa *et al.* (The Journal of Pharmacology and Experimental Therapeutics, 2003, Vol. 302, No. 2, pages 804-813) further underscores the unpredictability of attempts to associate single nucleotide polymorphisms with functional activity of OATPC. For example, Nozawa *et al.* were not able to detect any significant alteration in the transport activity of OATPC associated with four different single nucleotide polymorphisms.

The level of skill in the pertinent art is quite high, i.e. generally a PhD in biochemistry, but the unpredictability in the art is higher. While the instant specification has disclosed a number of different polymorphisms in the OATPC gene, it remains highly unpredictable as to the biological significance of these polymorphisms. While the specification teaches that the elected polymorphism results in an amino acid substitution in the encoded OATPC polypeptide, the specification is silent as to how this substitution effects the functioning of the encoded

polypeptide. Thus, the claimed method directed towards the detection of polymorphisms, or pharmacogenetic analysis following polymorphism detection, for enablement of the full scope, requires the knowledge of unpredictable and potentially non-existent associations between the instantly elected polymorphism and some phenotypic or activity trait. Even if the elected polymorphism is in some way associated with some disease or has an effect on the ability of OATPC to transport a substrate, it is difficult (if not impossible) to know or predict from the teachings of the specification which disease or substrates would be effected or how the polymorphism is associated. That is, it is unpredictable as to whether the presence of a particular allele the polymorphism would confer a higher or lower likelihood of having the disease or higher or lower transport activity of a given substrate. In this case, the possible uses for the claimed methods are undefined, beyond the suggestion that they can be used to detect a disease or an activity associated with the OATPC gene prior to treatment with a OATPC drug.

Quantity of Experimentation

The quantity of experimentation required to discover how to use the instant invention is very high. In order to use the claimed invention, one would have to establish a relationship between the polymorphism at nucleotide 1561 in a sequence of the OATPC gene as defined by the position in SEQ ID NO: 1 some physiological or disease state or any one of the many possible drugs that are transportable by OATPC. However, in view of the state of the art at the time the invention was made, and in view of the unpredictable nature of this art endeavour, the success of such experimentation is highly unpredictable. Indeed, even to use the method of claim 1 to identify patients suited for particular pharmaceutical agents, one would need to know that the polymorphism at nucleotide 1561 in a sequence of the OATPC gene as defined by the

position in SEQ ID NO: 1 was in some way associated with response to some pharmaceutical agent. In order to obtain the type of information necessary to practice the claimed invention, one would be required to undertake the screening of hundreds or thousands of patients as well as possible hundreds of diseases or pharmaceutical agents. Even if such experiments were undertaken, it would still be unpredictable as to whether any associations would be detected, in light of the unpredictability of such associations, as already discussed. Thus, while one could perform further research to determine whether applicant's method would be useful in disease detection and/or treatment and/or predicting response to drugs, it is unknown as to what the outcome of such research might be and as to whether any quantity of experimentation would result in the identification of an association between the polymorphisms at position 1561 of SEQ ID NO: 1 and any disease or condition or particular drug. Further, absent a teaching that the polymorphism at position 1561 of SEQ ID NO: 1 is not associated with such conditions or responses, it is further unpredictable as to whether detection of the polymorphism would be useful in predicting, e.g., a patient's response to drugs transportable by OATPC.

Furthermore, it is noted that the practice of the invention of claim 31 requires the using the sequence to assess pharmacogenetics of a drug transportable by OATPC. The specification teaches that OATPC has been demonstrated to be involved in the transport of some xenobiotics and statins, as well as thyroid hormones and conjugated steroids. However, the specification does not disclose a relationship between the transport of any with these drugs and the polymorphism at position 1561 in a sequence of the OATPC gene as defined by the position in SEQ ID NO: 1. The identification of a relationship between and the elected polymorphism would be highly unpredictable, requiring an extensive amount of research and experimentation.

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Furthermore, the scope of the claims includes the assessment of a possible relationship or the knowledge of a possible relationship between the OATPC polymorphisms and any number of hundreds of thousands of possible drugs that may be transported by this anionic transporter that is produced in the liver.

Thus, in light of the nature of the invention, the state of the art, the high level of unpredictability in the art, the lack of direction or working examples in the specification, and the high quantity of experimentation that would be required to practice the claimed invention, it is concluded that undue experimentation would be required to use the instantly claimed invention. Considering all of the factors discussed herein, it is concluded that it would require undue experimentation to determine the particular drugs whose transport would be effected by any of the polymorphisms taught in the instant specification, or the elected polymorphism in particular, and thus to practice the claimed invention commensurate in scope with the present claims.

Conclusion

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.


The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this

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application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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Juliet C. Switzer
Primary Examiner
Art Unit 1634

January 30, 2007